

510(k) Summary

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Device: Kinemax® Plus Tibial Spacers

The Kinemax® Plus Tibial Spacers are intended to be used with the tibial baseplates of the Kinemax® Plus and Kinemax® Plus Superstabilizer total knee systems in primary or revision total knee replacement procedures where there is bone loss on the tibia that requires augmentation for stability. The spacers may be cemented to the baseplate, or may be mechanically locked into place with fixation screws or fixation pegs. The baseplate-spacer assembly is then cemented onto the prepared proximal tibia.

There are three types of spacers in the Kinemax® Plus Tibial Spacer System: a half spacer, a full spacer, and a full angled spacer. These spacers are fabricated from cast Vitallium® alloy. The fixation screws and pegs used to secure these spacers to the tibial baseplates are fabricated from wrought or cast Vitallium® alloy. These products will be sold sterile.

The Kinemax® Plus Tibial Spacers are substantially equivalent to other legally marketed products. Examples of these products are listed below:

1. Duracon® Tibial Wedges - Howmedica (K915512)
2. Kinemax® Angled Tibial Wedge - Howmedica (K884837)
3. Insall-Burstein II Half and Full Tibial Wedges - Zimmer (K872379)
4. Maxim Tibial Augmentation Blocks - Biomet (K915132 and K922285)
5. CKS Tibial Spacers - Techmedica (K896542, K901457, K903286, and K914072)

An analysis of equivalent features was presented.

For information contact:

Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7431
Facsimile: (201) 507-6870